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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,835

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Rolf Muller

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BACHMAN & LAPOINTE, P.C.

900 CHAPEL STREET

SUITE 1201

NEW HAVEN, CT 06510

EXAMINER

ANDERSON, JERRY W

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,835	<b>Applicant(s)</b> MULLER ET AL.	
	<b>Examiner</b> JERRY W. ANDERSON	<b>Art Unit</b> 4152	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

## DETAILED ACTION

### *Specification*

1. The use of the trademarks i.e. NOVELOSE, ACTISTAR CRYSTALEAN etc. has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### *Claim Objections*

2. **Claim 7** is objected to because of the following informalities: the claim is dependent upon claim 6; however, it refers to claim 6 twice. The second referral to claim 6 should be deleted. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claim 3** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. **Regarding Claim 3**, the term “swelling level” renders the claim indefinite because the degree of swelling depends on the composition of any of the many different

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possible swelling liquids that may be utilized, environmental factors, and the measurement method. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-10** are rejected under 35 U.S.C. 102(b) as being anticipated by Y-C. Shi, U.S. Pat. # 6,890,571.

8. **Regarding Claim 1**, the Applicant claims a slow digestible starch, partially gelatinized, with a DSC melting point is >60 deg C, and initial hydrolysis rate (Ho) is reduced by > 10 %, Shi teaches a resistant, gelatinized starch, (lines 6-9 col. 3, lines 46-48 col. 4, '571, ) a starch that is resistant to digestion in the small intestine, and passes into the large intestine, ( line 13-15 col. 1 '571) a DSC melting point of at least about 90 deg. C (line 50-53 col. 4 '572), and digestibility being reduced to less than 50 % in two hours. (lines 5-14 col. 1 '571)

9. **Regarding claim 2**, Shi in '571 discloses the claimed invention, including hydrolysis rate being constant for at least 10 min, and less than 600 %/hr, as discussed below. The applicant determines the hydrolysis rate by measuring the amount of undigested starch at intervals of 15, 30, 45 and 60 minutes and calculating the digested

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portion of the starch. This data is plotted in Figures 1, 2, and 3. (pg 49 Applicant's specification) Shi measures the amount of glucose generated in the digestion reaction to give the digested portion of the starch at 20 min and 120 min. (lines 13-15 col. 7 '571) defines a rapidly digestible starch as being totally digested within 20 minutes. ( lines 52-54 '571) Shi compares the amount of digested starch at 120 minutes with the amount at 20 minutes, to arrive at an estimate of the resistant starch. (lines 22-27 col. 7 '571) In the Applicant's data, Shi's rapidly digestible starch corresponds to Fig 1 Kellogg's corn flakes, and Fig. 3, Sample set WS-57 1-4. Applicant in Table 2 lists the Ho%/h for sample set WS-57-1 from 800 to 1000. Shi in Tables 1 and 2 lists the amount of starch digested at 20 minutes ranging from 20 to 50 % of the total starch, and 120 minutes from 50 to 70 % digested. (Table 1 '571) Shi's slowly digestible starch fraction, in Table 1 is about 24 %/120 minutes or about 14.5 percent per hour. Comparable with the Applicant's values of 30 per cent per hour, Sample KS-1 Table 2, Applicant. However, as per the Applicant's Figs, 1-3 the curve is non-linear versus time, and thus, Shi's results are lower than the Applicants for digestion per hour. Looking at the 20 min values for Shi, and comparing to the Applicant's 15 and 30 minute values, it can be seen that the results for both methods are overlapping. (Table 1 and 2, '571, Figs. 1 and 2 Applicant)

10. **Regarding claim 4**, Shi discloses the claimed invention, as discussed above, including the DSC melting point of at least 70 deg. C. (lines 50-53 col. 4 '571)

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**11. Regarding claim 5**, Shi discloses the claimed invention, as discussed above, including that the short chain amylase content is about 98 % (line 44-48 col. 3 '571) and is highly crystalline short chain amylose. (lines 46-28 col. 4 '571)

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. **Claims 6-10** rejected under 35 U.S.C. 103(a) as being unpatentable over Y-C. *Shi*, U.S. Pat. # 6,890,571 in view of Y-C. *Shi*, U. S. Pat. # 5,593,503.

15. **Regarding claim 6 and 7**, '571 discloses the claimed invention, as discussed above, but lacks a discussion of the formation of the crystalline form of starch. ' 503 discloses a temperature range of 90-120 deg. C, moisture content of 30-40 %. (lines 53-61 col. 3 '503) Said values fall within the ranges of temperature, moisture content listed in the instant Claims 6 and 7.

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16. While the ranges of '503 and the instant claims differ in that '503 does not teach the exact same proportions as recited in the instant claims. One of ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the composition proportions taught by '503 overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that: "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in the disclosed set of percentage ranges is the optimum combination of percentages", *In re Peterson* 65 USPQ2d 1379 (CAFC 2003)

17. '571 and '503 are analogous art in the both are concerned with the modification of starches to form a starch that is resistant to digestion in humans.

18. It would have been obvious to a person having ordinary skill in the art at the time of the invention to combine the teachings of '571 and '503 in order to produce a food product that is likely to be a factor in the prevention of diverticulosis and colon cancer. (lines 30-32 col. 1 '503), and to produce a resistant starch that may contribute to reducing the risk of developing diabetes, or be useful in the treatment of hyperglycemia and obesity. (lines 36-40 '571)

19. **Regarding claim 8 and 9**, '571 discloses the claimed invention, as discussed above, but lacks a discussion of foodstuffs made with the modified starch. '503

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discloses a food products, cereal, bread, crackers, cookies, pasta, coated and fried foods, made using said modified starch. (Lines 40-45 col. 4, Claim 27 '503)

20. **Regarding claim 10**, '571 discloses the claimed invention, as discussed above, but lacks a discussion of increased organoleptic qualities such as crispiness, or preservative effects. '503 discloses that food products had good taste and appearance. (line 46, col. 9 '503, had acceptable mouthfeel and flavor, (line 67 col. 9, lines 30-31 col. 10, '503).

### ***Conclusion***

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY W. ANDERSON whose telephone number is (571)270-3734. The examiner can normally be reached on 7 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on 571-272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jwa

/Joseph S. Del Sole/  
Supervisory Patent Examiner, Art Unit 4152